K040531

TERUMO MEDICAL CORPORATION
SPECIAL 510(k) – SURGUARD2™ SAFETY NEEDLE
Section II. Summary & Certification

MAR 2 3 2004

SUMMARY OF SAFETY & EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

A. Device Name

Proprietary Device Name: TERUMO® SURGUARD2™ SAFETY NEEDLE

Classification Name: Needle, Hypodermic, Single Lumen with antistick

B. Reason for Submission:

This 510k is being submitted to extend the cleared SURGUARD2™ Safety Needle (K031453) product line to include 26 to 30gauge needle sizes taking into consideration the potential issues of safety and effectiveness specific for sheathing a smaller/thinner needles after use. This 510k will provide supporting information that the SURGUARD2™ Safety Needle design is safe and effective for smaller needle sizes (26 to 30g) and an acceptable extension of the current cleared SURGUARD2™ Safety Needle device (K031453).

C. Intended Use:

The SURGUARD2™ SAFETY NEEDLE device for 26 to 30gauge needles is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo Safety Needle is compatible for use with standard luer slip and luer lock syringes.

Additionally, after withdraw of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

Note: This is the same intended use as the predicate device, SURGUARD2™ SAFETY NEEDLE (K031453).

D. Description

The SURGUARD2™ SAFETY NEEDLE consists of a hypodermic needle with a hinged safety sheath attached to the connector hub. The safety sheath contains a locking mechanism which is activated when the sheath is manually pressed over the needle immediately after use and just prior to disposal to minimize the possibility of sharps injury. The safety sheath is activated with a one-handed operation by pressing the sheath against a firm surface. The locking mechanism is located at a designated position within the body of the short or long sheath appropriate for the needle size it is to contain. The needle gauge sizes are 26gauge to 30gauge and the needle lengths are 3/8" (9mm) to 1" (13mm). The hinge feature allows the user to set the sheath to the desired position for use. For user convenience, when the needle is in the "bevel up" position the sheath is located to the right. The SURGUARD2™ SAFETY NEEDLE will be individually packaged and sterilized as a safety needle only or as a safety needle with attached Terumo syringe.

E. Substantial Equivalence

The SURGUARD2™ SAFETY NEEDLE is substantially equivalent in intended use, design, technology/principals of operation, materials, and performance to the SURGUARD2™ SAFETY NEEDLE cleared under K031453 and TERUMO® Hypodermic Needles cleared under K771203 and K012646.

Differences between the devices do not raise any significant issues of safety and effectiveness.

F. Principals of Operation/Technology

The proposed SURGUARD2™ SAFETY NEEDLE for 26 to 30g needles and the predicate SURGUARD2™ SAFETY NEEDLE (K031453) and TERUMO® Hypodermic Needles (K771203 & K012646) are operated manually.

G. Materials

The materials used for the SURGUARD2™ SAFETY NEEDLE for 26 to 30gauge needles are identical to the materials used for the cleared SURGUARD2™ SAFETY NEEDLE (K031453) and TERUMO® Hypodermic Needles (K771203 & K012646).

H. Specifications

Product Description
26gauge x 1" (13mm) safety needle
27gauge x 1" (13mm) safety needle
30gauge x 1" (13mm) safety needle
26gauge x 3/8" (9mm) safety needle with attached 1cc syringe
27gauge x 1" (13mm) safety needle with attached 1cc syringe

I. Performance

The following tests were performed on the SURGUARD2™ SAFETY NEEDLE for 26 to 30gauge needles:

- Activation Force
- Deactivation Force
- Puncture Resistance
- Simulated Use Study

A risk analysis was conducted and any new or different issues of safety and effectiveness were identified and mitigated appropriately.

The SURGUARD2™ SAFETY NEEDLE submitted in this 510k for 26 to 30gauge needles is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the legally marketed predicate SURGUARD2™ SAFETY NEEDLE device (K031453) and TERUMO® Hypodermic Needles (K771203 & K012646).

J. Additional Safety Information

Manufacturing controls include visual, functional, and sterility tests.

The sterility of the device is assured using a sterilization method validated in accordance with ANSI/AAMI/ISO 11137-1998 Medical Devices – Validation and Routine Control of Radiation Sterilization. The SURGUARD2™ SAFETY NEEDLE is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

The Terumo SURGUARD2™ SAFETY NEEDLE is classified as Externally Communicating Device, Blood Path Indirect, Limited Duration of Contact (< 24 hr). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard

ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". Results of the testing demonstrate that the blood contacting materials are biocompatible.

K. Conclusion

The SURGUARD2™ SAFETY NEEDLE for 26 to 30 gauge needles without or with syringe attached is substantially equivalent to the SURGUARD2™ SAFETY NEEDLE cleared under K031453 and TERUMO® Hypodermic Needles cleared under K771203 and K012646.

Differences between the devices do not raise any significant issues of safety or effectiveness.

Date Prepared: February 27, 2004

Prepared by: Barbara Smith
Sr. Regulatory Affairs Specialist
Terumo Medical Corporation
125 Blue Ball Road
Elkton, Maryland 21921
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Fax#: 410-398-6079

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2004

Ms. Barbara L. Smith
Senior Regulatory Affairs Specialist
Terumo Medical Corporation
125 Blue Ball Road
Elkton, Maryland 21921

Re: K040531
Trade/Device Name: Terumo® Surguard2™ Safety Needle
Regulation Number: 880.5570, 880.5860
Regulation Name: Hypodermic Single Lumen Needle, Piston Syringe
Regulatory Class: II
Product Code: FMI, MEG
Dated: February 27, 2004
Received: March 1, 2004

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

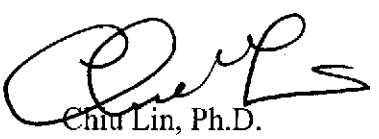
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-5618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040531

Indications for Use

510(k) Number (if known):

Device Name: TERUMO® SURGUARD2™ SAFETY NEEDLE

Indications For Use:

The SURGUARD2™ SAFETY NEEDLE device for 26 to 30gauge needles is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo Safety Needle is compatible for use with standard luer slip and luer lock syringes.

Additionally, after withdraw of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040531

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